REMARKS

Applicant and Applicant's attorney express appreciation to the Examiner and the Examiner's supervisor for the courtesies extended during the recent interview held on March 6, 2006. Reconsideration and allowance for the above-identified application are now respectfully requested. Claims 1-40 are pending, wherein claims 1-3, 30, 34 and 39 have been amended.

As discussed during the Examiner Interview, dental delivery systems according to the invention for whitening teeth include a barrier layer, such as a flexible strip of material or dental tray, and a dental bleaching composition that includes polyvinylpyrrolidone as a thickening agent in order to promote adhesion of the dental composition to a person's teeth during use. Problems associated with the use of carboxypolymethylene as thickening agent were discussed during the Examiner Interview, including the tendency of carboxypolymethylene to etch teeth if acidic and also to chelate teeth whether or not acidic. Such problems are discussed in the background section of the Application at pages 7-11.

The present invention seeks to reduce or eliminate calcium removal from tooth enamel caused by chelation of calcium ions by thickening agents composed of acrylic acid functional groups. Because carboxypolymethylene contains a high quantity of acrylic acid functional groups, it is both highly acidic and capable of chelating calcium ions. The present invention seeks to replace some, most or all of the carboxypolymethylene with polyvinylpyrrolidone. As discussed in the application at page 16, paragraph [0049], polyvinylpyrrolidone "contains no organic acid in its structure and therefore cannot etch or chelate teeth". Because of this, replacing any portion of carboxypolymethylene will provide some benefit due to reduced acid etching and/or chelation. Replacing most or all of the carboxypolymethylene will provide the greatest benefit.

During the examiner interview, Applicant's representative agreed to amend the claims as suggested to place the claims in condition for allowance over the art of record. The claims as amended are believed to comply with suggestions made by the Examiner and the Examiner's supervisor during the examiner interview.

Claim 1 recites a delivery system for delivering a dental bleaching composition to teeth while reducing calcium removal from tooth enamel comprising a water-resistant barrier layer and a dental bleaching composition, which is composed of a dental bleaching agent and polyvinylpyrrolidone as primary or sole thickening agent. Because polyvinylpyrrolidone is

defined as being the "primary or sole thickening agent", most or all of the carboxypolymethylene found in prior art bleaching strips, such as those disclosed in U.S. Patent No. 5,891,453 to Sagel et al., has been replaced with polyvinylpyrrolidone. Sagel et al. not only teaches that carboxypolymethylene is the preferred gelling agent but includes carboxypolymethylene in 5 of the 6 examples. Col. 8, ll. 41-44; col. 10, ll. 13-45. Whereas Sagel et al. discloses other gelling agents, such as carboxymethyl cellulose, poloxamer, and various gums, polyvinylpyrrolidone is not mentioned as one of the main gelling agents. Col. 8, ll. 36-48. Polyvinylpyrrolidone is only mentioned as one of several possible "additional gelling agents" that may optionally be used in combination with the main gelling agents, but in no specified amount. Col. 9, ll. 24-40. None of the examples in Sagel et al. include polyvinylpyrrolidone in any amount, let alone as the "primary or sole thickening agent". Thus, Sagel et al. provides no teaching or suggestion to select and include "polyvinylpyrrolidone as primary or sole thickening agent" within a dental bleaching composition.

To further emphasize the more benign nature of polyvinylpyrrolidone compared to the carboxypolymethylene employed in Sagel et al., claim 1 now emphasizes that the thickening agent promotes adhesion of the dental bleaching composition to tooth enamel without also removing calcium from tooth enamel by chelation. Because claim 1 defines a delivery system that includes a bleaching composition in which the thickening agent is less prone to attack tooth enamel by virtue of including "polyvinylpyrrolidone as primary or sole thickening agent", Applicant submits that claim 1 as amended is neither anticipated by, nor obvious over, Sagel et al.

U.S. Patent No. 5,670,138 to Venema et al. discloses oral care compositions containing a single type of tissue adhesion agent, which is a copolymer of N-vinylpyrrolidone and acrylic acid in a critical weight ratio of 60-95 parts N-vinylpyrrolidone to 40-5 parts acrylic acid. Col. 2, ll. 49-56. "Outside those ranges the effect of the improved bioadhesion does not occur, or only to a substantially lesser degree. A 50-50 copolymer does not have any effect and a homopolymer of N-vinylpyrrolidone does not have sufficient effect to be of any practical value." Col. 2, ll. 56-60 (emphasis added). It is therefore critical to the invention of Venema et al. for the copolymer to include acrylic acid groups within the stated ratio. Moreover, Venema et al. teaches away from compositions which include "polyvinylpyrrolidone as primary or sole thickening agent" as having no practical value. Therefore, even if one were to combine Venema et al. with Sagel et

al., the combined teachings would not teach or suggest a delivery system comprising a barrier layer and a dental bleaching composition that includes a bleaching agent and "polyvinylpyrrolidone as primary or sole thickening agent".

Claim 2 alternatively recites a delivery system that includes a barrier layer and a dental bleaching composition that includes a dental bleaching agent and polyvinylpyrrolidone having a molecular weight in a range of 1,000,000 to 1,500,000. As discussed in the application at page 16, paragraph [0051], the beneficial properties of polyvinylpyrrolidone decrease with lower molecular weight. Thus, higher molecular weights are preferred, as indicated by the examples, the majority of which include polyvinylpyrrolidone having a molecular weight in a range of 1,000,000 to 1,500,000. Application, pp. 18-19. Sagel et al., while allowing for the inclusion of polyvinylpyrrolidone, specifically teaches the use of polyvinylpyrrolidone having a molecular weight of about 50,000 to about 300,000. Col. 9, ll. 35-37. This is the only time Sagel et al. mentions a molecular weight for any gelling agent, which further emphasizes the criticality of using polyvinylpyrrolidone within this molecular weight range, if used at all. Sagel et al. neither teaches nor suggests a delivery system having all the elements recited in claim 2. Venema et al., on the other hand, teaches away from the use of polyvinylpyrrolidone altogether, regardless of the molecular weight. The molecular weights discussed in Venema et al. relate solely to the copolymers of N-vinylpyrrolidone and acrylic acid discussed above and are preferably less than 1,000,000. Col. 3, ll. 9-10. Accordingly, Applicant submits that claim 2 is patentable over Sagel et al. and Venema et al. even if combined.

Claim 3 alternatively recites a delivery system that includes a barrier layer and a dental bleaching composition that includes a dental bleaching agent and a thickening agent in an amount of at least about 25% by weight comprised of polyvinylpyrrolidone. Sagel et al. teaches up to about 15% of "gelling agents". Col. 8, ll. 31-32. Thus, the minimum quantity of thickening agent required in claim 3 is about 10 percentage points (or about 2/3 of 15%) greater than the maximum amount disclosed in Sagel et al. Venema et al., on the other hand, only discloses the inclusion of 0.01-5% of the copolymer of N-vinylpyrrolidone and acrylic acid. Col. 3, ll. 15-17[1]. Thus, the minimum amount of thickening agent utilized in claim 3 is about 5 times

[1] Venema et al. discloses that products in concentrated form that "must be diluted prior to use" may include between 2 to 50% of the copolymer. Col. 3, ll. 18-24. However, because such products "must be diluted prior to use", they are presumably unsuitable for use in the oral cavity without first being diluted.

greater than the maximum amount disclosed in Venema et al. Accordingly, even if one were to combine Sagel et al. and Venema et al., the combined teachings would not have motivated one of skill in the art to construct the delivery system of claim 3. Accordingly, Applicant submits that claim 3 is patentable over Sagel et al. and Venema et al. even if combined.

Independent claims 30, 34 and 39 are similar to claims 1-3 discussed above, but specifically recite the combination of a water-resistant flexible strip of material and a dental bleaching composition having the specific properties and characteristics that are similar or identical to those discussed above relative to claims 1-3. For this reason, Applicant submits that claims 30, 34 and 39 are patentable for at least those reasons given above relative to claims 1, 3 and 2, respectively.

As requested by the Examiner, Applicant is filing a Terminal Disclaimer concurrently herewith in order to overcome any actual or potential obviousness-type double patenting issues relative to any related patents and applications.

With respect to "references 101-109" not being considered (Office Action, p. 2), Applicant points out that these references were submitted during prosecution of U.S. Application Serial No. 10/770,489, filed January 27, 2001, which issued as U.S. Patent No. 6,500,408, and which is relied on for priority under 35 U.S.C. § 120.

In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by examiner amendment, the Examiner is requested to contact the undersigned attorney.

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Respectfully submitted,

JOHN M. GUYNN
Registration No. 36,153

WORKMAN NYDEGGER
Attorneys for Applicant
Customer No. 022913

JMG:ac
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